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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,252	08/31/2006	Takayoshi Kawaguchi	Q96699	4352
23373 7590 03/17/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER JONES, DAMERON LEVEST				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
03/17/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
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# Office Action Summary

**Application No.**

10/591,252

**Applicant(s)**

KAWAGUCHI ET AL.

**Examiner**

D L. Jones

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/8/10 & 8/31/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4-8 and 10-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8 and 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/31/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 8/31/06 wherein claims 1, 4-7, 10-16, 22, 25, and 28 were canceled and claims 2, 3, and 9 were canceled.

**Note:** Claims 1, 4-8, and 10-28 are pending.

### **APPLICANT'S INVENTION**

2. Applicant's invention is directed to a composition comprising a peptide, basic compound having the formula Z-Y-Leu-Phe-(X)<sub>n</sub>-Lys(NH<sub>2</sub>)<sub>m</sub>-epsilon(-(R)o-(T)i-U).

### **RESPONSE TO APPLICANT'S ELECTION**

3. Applicant's election without traverse of Group I (claims 1, 4-8, and 10-19) in the reply filed on 1/8/10 is acknowledged. Since Applicant did not point out the supposed errors in the restriction requirement, the restriction is deemed proper and is made FINAL.

**Notes:** It is duly noted that Applicant elected the species wherein the peptide is formyl-Nle-Leu-Phe-Nle-Tyr-Lys(NH<sub>2</sub>)-epsilon(-(Ser-D-Arg-Asp-Cys-Asp-Asp) was elected. Initially, the Examiner searched for Applicant's elected species; however, since no prior art was found which could be used to reject the claims, the search was expanded over the full scope of Group I.

### **WITHDRAWN CLAIMS**

4. Claims 20-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

## 112 FIRST PARAGRAPH REJECTIONS

### **Written Description Rejection**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4-8, and 10-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to what compounds or groups are encompassed by the instant invention for the variables T, U, Z, and X. In addition, it is unclear what nitrogen containing cyclic carboxylic acid compounds having 8-20 carbon atoms and derivatives thereof that are compatible with the instant invention (see claim 10, for example). Likewise, it is unclear what alkylene-amine carboxylic

acids having 4-10 carbon atoms are compatible with the instant invention (see claim 10, for example). Also, it is unclear what hydrophilic organic solvent, stabilizers, reductants, pH adjusters, and surfactants are useful with the instant invention. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

## **112 SECOND PARAGRAPH REJECTIONS**

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 4-8, and 10-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,4-8, and 10-19: The claim as written is ambiguous because it is unclear what particular basic organic compounds having an imidazole ring that are compatible with the instant invention. In addition, it is unclear what Z groups, protecting groups, Applicant is claiming that are compatible with the instant composition. Likewise, in regards to the variables X and T, it is unclear what spacer groups are encompassed by the instant invention. In addition, for the variables T and U, it is unclear what compound/group Applicant's is claiming that the variables may be.

Claim 6: The claim is ambiguous because it does not further limit claim 1. Specifically, the language of claim 6 refers to qualities that the peptide is 'capable of' performing, not limitations that are required for the functioning or attachment to the peptide. Applicant includes the phrase 'capable of'. However, Applicant is reminded that it has been held that the recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138).

Claims 7, 8, 10, 11, 13, and 16: The claims are ambiguous because the claim does not further limit claim 1. The phrase 'capable of' is not a positive limitation in the

claim. Likewise, claims 8, 10, 11, 13, and 16 include the 'capable of' language and do not further limit the require components of the composition.

#### **COMMENTS/NOTES**

9. It should be noted that no prior art has been cited against the instant invention. However, Applicant **MUST** address and overcome the 112 rejections above. In particular, the claims are distinguished over the prior art because the prior art neither anticipates nor renders obvious the specific composition as set forth in independent claim 1.

10. It is duly noted that throughout the claims, Applicant includes the phrase 'capable of'. However, Applicant is reminded that it has been held that the recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/  
Primary Examiner  
Art Unit 1618

March 14, 2010